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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS-5539-N]

RIN 0938-

Medicare Program; Extending the Medicare Diabetes Prevention Program's (MDPP)

Expanded Model Emergency Policy through CY 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Policy extension.

SUMMARY: This document is to alert Medicare Diabetes Prevention Program (MDPP) expanded model suppliers and interested parties that although current MDPP flexibilities permitted pursuant to regulations issued during the Public Health Emergency (PHE) for COVID-19 are scheduled to expire on May 11, 2023, we are specifying an effective date, for purposes of the regulations of December 31, 2023, through which in-person delivery of MDPP services can be suspended. This extended effective date applies for all MDPP suppliers to allow additional time to resume in-person services. MDPP suppliers may use all of or part of this period to extend the flexibilities described in the regulations. This document provides information to MDPP suppliers regarding the extension of the ability to suspend in-person services as the PHE for COVID-19 concludes.

DATES: Effective on [insert date of publication in the Federal Register], the PHE flexibilities described under 42 CFR 410.79(e) are extended through 11:59 PM EST on December 31, 2023. FOR FURTHER INFORMATION CONTACT: Mollie Howerton, (410) 786-5395, and Karen Abraham-Burrell, (410) 786-4789.

SUPPLEMENTARY INFORMATION:

I. Background On December 28, 2020, the Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), which modified certain Medicare Diabetes Prevention Program (MDPP) policies for the remainder of the COVID-19 Public Health Emergency (PHE), as well as during any future 1135 waiver event that we determine may disrupt in-person MDPP services (an "applicable 1135 waiver event"). Accordingly, under the amended regulation at 42 CFR 410.79(e)(3)(v), MDPP suppliers have been permitted to suspend in-person delivery of the set of MDPP services during the PHE and are required to resume in-person services either upon the end of the PHE or upon an effective date specified by CMS. The term "set of MDPP services" is defined at § 410.79(b) to mean the series of MDPP sessions, composed of core sessions and core maintenance sessions offered over the course of the MDPP services period. Under § 410.79(c)(iv), weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken during an "MDPP session," which is defined at § 410.79(b) to mean a core session or a core maintenance session.

The MDPP regulations provide for the following flexibilities during the PHE or an applicable 1135 waiver event:

• Alternatives to the requirement for in-person weight measurement (§ 410.79(e)(3)(iii)). Section 410.79(e)(3)(iii) permits an MDPP supplier to obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss-based performance achievement goals in the following manner: (1) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or (2) via self-reported weight measurements from the athome digital scale of the MDPP beneficiary. We stated that self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale. Alternatively, the MDPP beneficiary may self-report their weight by submitting to the MDPP supplier a date-stamped photo or video recording

of the beneficiary's weight, with the beneficiary visible in their home. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on the digital scale on the date associated with the billable MDPP session. This flexibility allows suppliers to bill for participants achieving weight loss performance goals.

• Elimination of the maximum number of virtual services (§ 410.79(e)(3)(iv)). The virtual session limits described in § 410.79 (d)(2), and (d)(3)(i) and (ii) do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in 42 CFR 400.200 or applicable 1135 waiver event. Under this provision, MDPP suppliers are permitted to provide MDPP services virtually during the PHE, as long as the virtual services are furnished in a manner that is consistent with the CDC Diabetes Prevention Recognition Program (DPRP) standards for virtual sessions, the curriculum furnished during the virtual sessions addresses the same curriculum topics as the CDC-approved National Diabetes Prevention Program (National DPP) curriculum, the supplier has an in-person DPRP organizational code, and other requirements specified at § 410.79(e)(3)(iv) are satisfied. For more information on the MDPP flexibilities allowed during the PHE, please see

https://www.cms.gov/files/document/participants-medicare-diabetes-prevention-program-cms-flexibilities-fight-covid-19.pdf.

For purposes of § 410.79(e)(3)(v), we are specifying an effective date of December 31, 2023, through which MDPP suppliers may suspend in-person delivery of the set of MDPP services. We recognize that extending the suspension of in-person delivery of the set of MDPP services would not be useful without also extending the PHE flexibilities permitted under § 410.79(e)(3)(iii) (regarding use of alternative methods for obtaining weight measurements during virtual services) and § 410.79(e)(3)(iv) (regarding elimination of the maximum number of virtual services). Therefore, we are extending the PHE flexibilities at § 410.79(e)(3)(iii), and (iv), to ensure that MDPP suppliers can continue delivering the set of MDPP services on a virtual

basis, including all core and core maintenance sessions as well as the collection of body weight measurements.

Given the 3-year duration of the COVID-19 PHE, we anticipate that MDPP suppliers will need time following the end of the COVID-19 PHE to resume in-person services for reasons that may include securing an available physical location that meets organizational and beneficiary needs, recruiting coaches, educating new and existing beneficiaries about in-person sessions, and adjusting messaging regarding the delivery modality of MDPP. Based on feedback from MDPP suppliers, interested parties, CDC DPRP and National Diabetes Prevention Program staff, we anticipate that MDPP suppliers may require at least 6 additional months to adequately prepare to resume in-person services from an operational perspective as well as allow time for us to consider doing additional rulemaking. Therefore, we will allow MDPP suppliers to utilize the period covering May 12, 2023, through December 31, 2023, to resume in-person services through the use of all or part of this period to extend the flexibilities described in § 410.79(e), to allow for an orderly transition of the flexibilities enabled by the PHE for COVID-19.

II. Provisions of this Document

We established and implemented policies for MDPP in response to the COVID-19 PHE to support our goals of ensuring beneficiary access to necessary services and maintenance of these services. Although we previously informed MDPP suppliers and interested parties that they must be prepared to resume in-person services following the end of the PHE, MDPP suppliers may continue to utilize the MDPP flexibilities allowed under § 410.79(e) through December 31, 2023, to maintain the continuity of services for both suppliers and beneficiaries as the public transitions out of the COVID-19 PHE. Under § 410.79(e)(3)(v), we allowed MDPP suppliers to suspend the in-person delivery of MDPP when necessary due to an applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by us. Given the 3-year duration of the PHE, we anticipate that MDPP suppliers will need additional time to resume in-person services

due to reasons such as possible site inactivity, supplier inactivity, or challenges regarding in-

person beneficiary recruitment. MDPP suppliers may use this period to continue the flexibilities

described under § 410.79(e), in recognition of the variable effects of the PHE for COVID-19 on

both MDPP suppliers and Medicare beneficiaries.

The Administrator of the CMS, Chiquita Brooks-LaSure, having reviewed and approved

this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to

electronically sign this document for purposes of publication in the Federal Register.

Dated: April 26, 2023

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

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